EFFECTS OF STRUCTURED EXERCISES AND YOGA DURING FOLLICULAR AND LUTEAL PHASE ON PELVIC ALIGNMENT, MENSTRUAL DISTRESS AND QUALITY OF LIFE IN PRIMARY DYSMENORRHEA

SHORT SYNOPSIS

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Certificate

I hereby declare that the short synopsis "**Effects of Structured Exercises and Yoga during Follicular and Luteal Phase on Pelvic Alignment, Menstrual Distress and Quality of Life in Primary Dysmenorrhea**" being submitted in partial fulfillment of the requirement for the degree of Doctor of Philosophy in Physiotherapy, under School of Allied Health Sciences Manav Rachna International Institute of Research & Studies, Faridabad during the academic year 2022. It is a bona fide record of original work carried out under the supervision of Dr. Kshitija Bansal and has not been submitted in full or part to any other university or institute for degree or diploma. Further, it is certified that short synopsis is plagiarism free and proof has been submitted.

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ABSTRACT

Primary dysmenorrhea (PD) is defined as menstrual cramps without any pelvic origin pathology, which occur from the first day till third day of menstruation phase. During each menstrual cycle sex hormones fluctuates which can impact muscle strength and endurance. Primary dysmenorrhea is most common gynaecological problem which can cause decrease in quality of life (QoL) in females. This study will have 4 groups in which yoga and structured exercise regime will be performed by selected females having primary dysmenorrhea, in luteal or follicular phase. Assessment of primary dysmenorrhea will be done by a self-administered questionnaire, severity of menstrual symptoms will be assessed by Menstrual Distress Questionnaire (MDQ), QoL by Health-Related Quality of Life questionnaire and pelvic anterior and posterior tilt by PALM palpation meter. Baseline assessment and post intervention assessment of the parameters will be done and using SPSS analysis will be performed.

Key words – Primary dysmenorrhea, menstrual distress, follicular phase, luteal phase, structured exercises, yoga, pelvic alignment, quality of life.

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INTRODUCTION

Menstrual cycle is the cyclic shredding of lining of the uterus. The menstrual cycle is divided into four phases, (i) follicular phase, (ii)ovulation, (iii) luteal phase and (iv) menstruation phase. (Treloar A.E et al 1967) Average duration of the menstrual cycle is for 28 to 35 days. (Mihm M et al 2011) It has been well-established that the concentration of estrogen, progesterone, luteinizing hormone (LH) and follicle stimulating hormone (FSH) fluctuates during the 4 phases of menstrual cycle. In the early follicular phase, the level of estrogen & progesterone is low, whereas in the mid luteal phase estrogen & progesterone are in high concentration levels. [Friden C et al 2006]

Estrogen and progesterone have different physiological effects. In the skeletal system these hormones effect by decreasing the fibroblastic activity, which in addition decreases the collagen production in tendon [Janse de Jonge et al 2001]; the hormones also have effects on muscular strength, endurance and postural control. [Bryant AL et al 2011, Darlington CL et al 2001] Skeletal muscles have estrogen receptors which changes the motor control and various patters in which force is transmitted in human body. [Aline et al 2017]

Dysmenorrhea is cramping pain of uterine origin which occurs during the menstruation. It is one of the most recurrently encountered problem faced by females in their fertile age. The areas which usually experience pain are, abdomen, lower back, pelvis & thighs. But the symptoms are not just limited to cramping pain to specific areas but there are other symptoms which also accompanied namely; nausea, vomiting, diarrhoea, dizziness, fatigue, headache and sleep disturbances. [Lacovides S et al 2015]

Dysmenorrhea is divided into 2 types, that are primary dysmenorrhea (PD) & secondary dysmenorrhea (SD). Primary dysmenorrhea origin is idiopathic and starts usually after 6-12 months of menarche but secondary dysmenorrhea is linked with pelvic pathology and starts after few years of menarche and is associated with some pathology of pelvic and systemic origin. [Latthe P et al 2015, Fraser et al 1992, Rosalie et al 1943] SD can be caused due to endometriosis which has been observed as one of the most common cause for it; other causes are, ovarian cysts, intra-uterine adhesions, pelvic inflammatory disease or any other pelvic origin pathology. [Andersch B et al 1982, Dawood Y et al 2008] Primary dysmenorrhea initiates around 8 hours on the first day of menses and last for 3 days. [Proctor et al 2007] 88% of pubescent females suffer from pain during menstruation within 2 years after their first cycle. [Harlow et al 1996]

One of the most often encountered gynaecological problem is PD. [Burnett M et al 2017, Hy Z et al 2020, Subasinghe KA et al 2016] Associated symptoms of PD has been discussed in previous studies and approximately 85.9 % females suffer from abdominal pain, 79.3% suffer from tiredness, 50% have irritability, 29.3% suffer from headache, 54.5% suffer from nervousness, 52.7% have tender breasts and 28.6% suffer from joints pain [Hailemeskel S et al 2016, Ortiz MI et al 2010, Pernandez et al 2018, Ozerdogan et al 2009]

Females with secondary dysmenorrhea usually have no history of menstrual cramps, and a sudden rush of symptoms like bleeding in between the two menstrual cycles, irregularity of menses, menorrhagia, increase in intensity of pain during menses are observed. [Amimi S et al 2013]

The prevalence of primary dysmenorrhea ranges about 25% - 90% females worldwide. [Okusanya et al 2009] It affects 90% of females who have regular & cyclic menstrual cycle. [Weissman et al 2004] Females aged between 17 to 24 years are more prone and its prevalence rates are 67%-90%. [Harlow et al 1996, Kennedy et al 1997] Studies have found that it is one of the leading problems from which females are suffering from and about 90% of adolescent girls have PD. [Berkley et al 2013] In a study done in India, 70.2% females were suffering from primary dysmenorrhea in the selected population. [Shabnam et al 2016] Unmarried females are more frequently suffer from PD as compared to married females. [Harlow et al 1996]

The cause for PD is not limited to just one but various causes; the most widely known cause for primary dysmenorrhea is over production of prostaglandins in uterus, which brings about high amplitude contractions in uterus which causes pain of different intensities to different females. These contractions help in discharging of blood from endothelium. [Bulletti et al 2000] Prostaglandins cause the blood supply to decrease as the blood vessels constrict which relatively causes hypoxia and ischemia in the uterus, surrounding musculature & also increased sensitivity of the nerve endings which ultimately causes pain in lower abdomen and pelvis also the systemic symptoms accompany with pain like nausea, vomiting and diarrhoea. [Mendiratta V et al 2017, Bernardi et al 2017, Lacovides et al 2015]

Pelvic stability is linked with passive and active elements; passive elements are ligaments and bones whereas the active elements are muscles and tendons. The active and passive elements work together for smooth functioning and stability around the pelvis. [Panjabi MM et al 1992] Former studies have also found out that pelvic malalignment can increase the symptoms of primary dysmenorrhea, thus a relationship between primary dysmenorrhea has been seen

because of tension in the connective tissues increases which later also changes the positioning of uterus. [Margaret et al 1975] It has been observed in earlier studies that increased stress in the ligaments which connect sacral vertebra to uterus also tends to increase the pain during menstruation. [Gender W et al 2003]

Some biological, psychological and lifestyle factors also are linked with causes of primary dysmenorrhea. Biological factors are early onset of menarche, menorrhagia, family history of PD, occurrence of premenstrual syndrome (PMS); psychological factors include stress, anxiety, emotional problems, depression; lifestyle factors include diet, social status, smoking, alcohol consumption, tobacco intake, caffeine consumption in excess & living environment. [Ortiz et al 2009, Zegeye DT et all 2009, Dorn LD et al 2009, Ju H et al 2014, Fernandez et al 2018, Tonini et al 2002, Latthe P et al 2006] Other factors are increased or decreased BMI, level of physical activity and core strength. [Hailemeskel S et al 2016, Balbi et al 2000, G. Lakshmanan et al 2017]

It is a condition which almost every female is facing and pain is a significant symptom which causes absenteeism in educational institutions and offices. [Shabnam et al 2016] About 2-28% females experience chronic pain which hampers their daily routine activities. [Ju H et al 2014] The impact of PD is vast; females tend to avoid various social gatherings which has a deleterious effect in relationships with family, friends, peers and colleagues. [D.C Potur et al 2014], E. Fernandez et al 2019] A noticeable deterioration in academic performance and sports activities is seen in students. There is a decline in attendance, marks, homework submissions, learning and concentration during lectures. [M.I Ortiz et al 2009, C. Banikarim et al 2000]

This has caused decline in quality of life of females suffering from PD which results in bad outcome at work too. Quality of life (QoL) is defined as a phenomenon which is subjective in nature and is based on individual's believes, perception and past experiences. [Joshi T et al 2015] PD also impacts female's sleep quality, interactions in social gatherings, working schedule which hampers the overall QoL. [Jones G et al 2004, Aziato L et al 2014, Razak AM et al 2020] Almost 10% of females who suffer from dysmenorrhea are bedridden for 1-3 days of each menstrual cycle, this leads to tremendous increase in absenteeism from school, college and workplaces. [Ballantyne et al 2013] The overall increased percentage of absenteeism from work of females due to pain has led to 600 million work hours wastage and economically a huge loss of 2 billion dollars. [Avasarala AK et al 2008]

In India quite a few visits gynaecologists for medical advice for pain relating to PD, they either take home remedies or do not go to work. [Jones G et al 2004, Aziato L et al 2014, Razak AM et al 2020] Females have considered pain as a normal illness and do not inquire or go for check-ups to the gynaecologists. [Ballantyne et al 2013]

Traditionally NSAIDs and contraceptives were the choice of treatment for PD by the females but recently, studies have discussed that these medications have ill effects on female body like headaches, nausea, vomiting, sleepiness, heartburning sensation and indigestion. [French L et al 2008, Ryan SA et al 2017, Camlibel M et al 2019] There are also adverse effects of the drugs which includes bronchospasm, edema, haematological problems, nephrotoxicity and fluid retention. [French L et al 2008, Ryan SA et al 2017] Mefenamic acid is one of the most preferred and safest drug for the treatment of PD. [Marjoribanks J et al 2010, Feng X et al 2018] But quite recently it has been established by The Indian Pharmacopoeia Commission (IPC) that Meftal or mefenamic acid has adverse drug reactions eosinophilia and systemic symptoms (DRESS) syndrome.

Recent studies have reported that females who tend to be more physically active has less symptoms of PD. Thus, treatment of dysmenorrhea can be done by different aerobic exercises, yoga, physiotherapy, Pilates etc and these treatments do not have any detrimental effects in the body also. [Zahradnik et al 2009, Uysal et al 2017] Nam -Young in his study told that yoga is effective is reduction of PD. Yoga helps to improve overall health of the individual, muscle flexibility and strength and improves quality of life by also decreasing pain. [Rakhshae et al 2011] Yoga helps to relieve stress and makes the individual feel tranquility also mind and body relaxes at the same time. [Carlson et al 1996] Earlier studies have obsered that yoga is effective for various orthopaedic conditions such as low back pain, osteoarthritis and deformities like kyphosis. [Cheung et al 2017, Greendale et al 2002] There are some studies which have reported that yoga poses can reduce pain during menstruation. [Sutar et al 2016] Yoga combines together breathing techniques, different poses and meditation which augments overall health of an individual. [Hofmann et al 2016]

Exercises tend to decrease the pain during menstruation, many authors in their studies have concluded that stretching and strengthening exercises have given good results by improving the symptoms of PD. [Rajalakshmi et al 2016] Former studies which have been done discuss about different exercises but very few studies have been done which have made a structured exercise program for the management of symptoms of PD. Thus, a study which will explain

that which management is better suitable for females with PD is need of the hour and it will also explain if the management can improve overall quality of life of those females.

LITERATURE REVIEW

Effect of Menstrual phases on the physical & functional performance of females

Aline et al performed a study to find the influence of various phases of menstrual cycle in functional performance; they selected 13 healthy females. For the assessment of functional performance Figure of eight hop test, modified star excursion balance test and side hop test were explained to the females & were performed by females in 3 phases of menstrual cycle, that were menstruation phase, ovulatory phase and luteal phase. The results found that functional performance of females was reduced in menstruation phase as compare to the other 2 phases.

Hamid et al did a study to measure difference in strength, endurance, power & changes in hormones during different phases of menstrual cycle. 20 females were selected, follicle stimulating hormone (FSH) & luteinizing hormone (LH) levels were assessed by blood sampling. Anaerobic power assessment was done using RAST test, IRM was calculated for bench press & leg press for the assessment of strength, endurance was assessed using 60% of 1RM. All the measurements were taken at follicular phase, ovulatory phase & luteal phase. Results showed that the different phases of menstrual cycle do not limit performance of females.

Effect of primary dysmenorrhea on pelvic alignment

Moon Jeong Kim et al performed a study to find relationship of pelvic alignment with dysmenorrhea. Using VAS and MDQ they assessed the menstrual symptoms and pain and formation of two groups was done, one with dysmenorrhea and other without dysmenorrhea. The assessment for pelvic alignment was done with Formetric 4D in which pelvic torsion, trunk imbalance, lateral deviation, pelvic tilt, kyphosis, lordosis and surface rotation were measured. The results inferred that there is a relationship between pelvic torsion and dysmenorrhea.

Juehan Wang et al did a study to find relationship between spinopelvic alignment and primary dysmenorrhea. Thet made 2 groups, one group had patients with primary dysmenorrhea (120) and other group was of healthy individuals who didn't have pain during menses (118). For the assessment of spinopelvic parameters, a full-length P-A radiography was done for all the participants. Assessment of lumbar lordosis, kyphosis, C7 sagittal vertical axis, pelvic incidence and sacral slope. The result showed that the increased menstrual pain is associated with sacral slope and pelvic incidence angles.

Moon Jeong Kim et al did a research to find effects of lumbar pelvic alignment and thickness of abdominal muscles on primary dysmenorrhea. Two groups were made of primary dysmenorrhea (28) and normal individuals (22). The thickness of abdominal muscles was assessed with ultrasound imaging and Formetric 4D was used to assess lumbo-pelvic alignment. Angles that were observed were pelvic tilt, rotation, pelvic torsion, scoliosis, lordotic angle. Abdominal muscles which were assessed are internal oblique, external oblique and transverse abdominis. There was a difference in lordotic angle, scoliosis and thickness of abdominal muscles in the two groups, thus malalignment in lumbar spine and abdominal muscles thickness can be associated with primary dysmenorrhea.

Effect of primary dysmenorrhea on quality of life

Stella et al did a study to find out association of menstrual pain in reduction of QoL in females with primary dysmenorrhea. They assessed QoL during different phases of menstrual cycle, one during menstruation and other at late follicular phase. QoL was being assessed using quality of life enjoyment and satisfaction questionnaire (Q-LES-Q-SF). It was found that females had a decreased QoL during menstruation and a good QoL was seen in same females during follicular phase.

Rami et al performed a study in Japanese females to find association between severity of dysmenorrhea and QoL. They formed two groups, one with dysmenorrhea (471) and other without dysmenorrhea (24). Numeric pain rating scale (NPRS) was used for measuring pain intensity & pain was classified as mild, moderate or severe. QoL was assessed using World Health Organization Quality of Life scale. The result showed females having severe pain during menstruation had poorest QoL, in fact they had poor psychological QoL too.

Elia et al performed a study to find the impact of dysmenorrhea on QoL in university students. 305 females completed a self-administered questionnaire and EuroQol-5 dimensions 5 level questionnaire to measure the QoL. The results concluded that females who were physically active had less pain during menstruation and dysmenorrhea has a huge impact in the QoL of young females.

Effects of exercises in treatment of primary dysmenorrhea

Manpreet et al has done a study to find the effects of combined exercises in managing the symptoms of primary dysmenorrhea. The intervention included flexibility training, strengthening of core, endurance and Kegel exercises. 30 minutes session was done for two

times a week for 8 weeks. Intensity of menstrual pain was measured by VAS. The results showed that combination of exercises can reduce menstrual pain.

Rajlaxmi et al conducted a study to find the effectiveness of core strengthening and stretching in females having primary dysmenorrhea. 2 groups were formed, Group A performed stretching and group B performed core strengthening exercises. Core strengthening exercises were performed for 4 days 2 times a day for 20 mins, it was continued till 4 months. Stretching was performed for 4 days 2 times a day for 10 minutes till a period of 7 weeks. The results inferred that stretching was more effective in managing the symptoms of PD and also QoL of females also improved.

Effects of yoga in treatment of primary dysmenorrhea

Lorensia et al conducted a study on finding the effectiveness of yoga on menstrual pain and QoL. Pain intensity was measured using Numeric pain rating scale, QoL was assessed using Pediatric Quality of Life Inventory Questionnaire. For 6 weeks yoga was done once a week, 30 mins per session. The results showed that menstrual pai was reduced and QoL was improved in females after doing yoga.

Prahardian et al conducted a study where they discussed about the effects of yoga asanas in dysmenorrhea. The study had 2 groups, one was control group and other was experimental group in which yoga intervention was given. Yoga was performed 3 times a week and 45 minutes session were given. The results concluded that yoga did not have any significant effects for managing dysmenorrhea.

RESEARCH GAP & PROBLEM STATEMENT

Research gap

Studies have been done previously discussing about various managements for primary dysmenorrhea but no study has assessed which menstrual phase best suits for the treatment of symptoms of primary dysmenorrhea, pelvic alignment and quality of life.

In each menstrual phase level of estrogen and progesterone changes, former studies have explained that estrogen receptors are present over the skeletal muscles which can change force transmission of muscles & facia but there is a dearth of literature which has discussed which phase of menstrual cycle should be chosen for the management of primary dysmenorrhea.

Also, barely any literature has be found which has made a structured exercise program for the management of primary dysmenorrhea; thus, a study to create a structured exercise regime and comparing its effects with yoga can be helpful clinically for choosing the better treatment protocol for treating menstrual distress.

Problem Statement

Previous studies have explained about effects of yoga and other physical exercises in managing primary dysmenorrhea, also the previous studies have chosen luteal phase for treating primary dysmenorrhea but has not mentioned any specific reason for selecting this menstrual phase; thus, there is insufficient literature comparing the effects of yoga and structures exercises given during follicular & luteal phase on pelvic alignment, menstrual distress and quality of life in females having primary dysmenorrhea.

DESCRIPTION OF TOPIC

The present study will be dealing with females who have primary dysmenorrhea, which will be diagnosed with self-administered questionnaire and severity of the symptoms will be assessed by Menstrual Distress Questionnaire (MDQ).

Females who will be selected through inclusion criterion will be assessed for anterior and posterior pelvic tilt by PALM palpation meter and QoL through Health-Related Quality of Life (HRQoL) questionnaire. Females will be divided into 2 main groups; one group will be treated in luteal phase and other in follicular phase and a subdivision will be done where the treatment, with the structured exercise regime and other will be treated with yoga. The treatment will be given for consecutive four menstrual cycles. After which females will be assessed again for menstrual distress, pelvic alignment and QoL.

RESEARCH AIM & OBJECTIVES

AIM - To find the effectiveness of Structured Exercises and Yoga performed in follicular and luteal phases of menstrual cycle on Pelvic Alignment, Menstrual distress and Quality of Life (QoL) in females with primary dysmenorrhea.

OBJECTIVES -

- To study the effect of structured exercises performed in follicular phase & luteal phase of menstrual cycle on Pelvic Alignment, Menstrual distress and QoL in females with primary dysmenorrhea.
- To study the effect of yoga performed in follicular phase & luteal phase of menstrual cycle on Pelvic Alignment, Menstrual distress and QoL in females with primary dysmenorrhea.
- To compare the effect of structured exercises and Yoga performed in follicular and luteal phase on Pelvic Alignment, Menstrual distress and QoL in females with primary dysmenorrhea.

RESEARCH METHODOLOGY

Study Population- Young Females (18-25 years) having primary dysmenorrhea

Study Design – Pre-post experimental design

Location – Delhi/NCR

Sampling Technique – Convenient Sampling with random allocation

Sample Size – 96 which was calculated by G power

With 20% drop outs

$N_1 = N / 1 – q$

$N_1 = 19 /1 - 0.20$

$N_1 = 19 / 0.80$

$N_1 = 27.14$

N_1 = 28 (for each of the 4 group)

28*4 = **96 [96 total sample size]**

Selection Criteria-

1. Inclusion Criteria-
    - Females with primary dysmenorrhea which will be diagnosed by self-administered questionnaire
    - MDQ questionnaire score more than 47
    - Age – 18 - 25 years
    - Menstrual cycle of 28 – 35 days
    - Unmarried females who are sexually inactive
2. Exclusion Criteria-
    - Uterine origin pathology (endometriosis, pelvic inflammatory disease, fibroids, adenomyosis, tumours, PCOD, PCOS, ovarian cyst, female genital tuberculosis, etc)
    - Any other gastrointestinal related problems like hernia, gall stones
    - Urogenital condition like renal calculi or recent (3 months) history of UTI or any other vaginal infection

- History of pregnancy or abortion or failed IVF
- Regular vigorous physical activity like gym/ yoga/ Pilates (IPAQ score = 1500 MET minutes per week)
- Any diagnosed musculoskeletal condition
- Recent history of trauma
- Psychological/mental illness
- On contraceptive pills
- Taking medications (e.g. Meftal - Spas) or any other treatment (e.g. Unani, Ayurvedic) or home remedies (e.g. ginger tea) for primary dysmenorrhea
- Under any hormonal therapy and steroids

Independent Variables- Yoga, physiotherapy treatment, menstrual cycle phases

Dependent Variables- Pelvic alignment (anterior-posterior and lateral tilt), quality of life & menstrual distress

Instrumental Tools Required- PALM palpation meter, Health related quality of life questionnaire (Cronbach alfa 0.905), Menstrual Distress Questionnaire (0.98)

Outcome variables –

1) Menstrual distress – Menstrual symptoms will be assessed with Menstrual Distress Questionnaire (MDQ), Form C. This questionnaire helps to report females' experience during phases of menstrual cycle and has questions relating to the most recent menstrual cycle. It includes 46 items which are answered by females using the Likert scale for scoring. It has questions relating to – pain, concentration level, changes in behaviour, autonomic reactions, negative effects, arousal, water retention and control. It has a maximum score of 188. The questionnaire grading is done by calculating the score; higher the score, more is the severity. A score of 47 indicated mild symptoms, 48-94 indicates moderate symptoms, 95-144 indicates strong symptoms and 145-188 indicates severe symptoms. In this study we will be taking females who have minimum score of 47.
2) Health-Related Quality of Life – The questionnaire comprises of 3 modules, in which one module asks questions related to healthy days, the second asks questions related to activity limitations and the third asks about physical and emotional health of the

individual. This estimates the total number of unhealthy days an individual had in the past 30 days.

3) Pelvic Alignment – It will be assessed using PALM palpation meter. It consists of a calliper and inclinometer. Validity for anterior-posterior pelvic tilt is 0.92 and for lateral tilt is 0.78.

Procedure –

Ethical approval from MRIIRS will be taken and females aged between 18-25 years will be screened for eligibility criterion. Consent will be taken from the selected females.

Determination of luteal and follicular phase: It will be done using a previous study by Eiling et al. Females having menstrual cycle of 28-35 days will be taken for the study and this will be estimated asking average length of previous 3 cycles. Ovulatory phase will be taken counting 14 days backwards from the next estimated date of menstruation. Luteal phase will be calculated counting 7 days from the ovulatory phase. Days when the bleeding occurs is the menstruation phase, when bleeding gets over then it is the initiation of follicular phase which lasts till the ovulatory phase.

This study will be divided into two phases; in phase one a pilot study will be conducted for the establishment and validation of structured exercise regime for management of females with PD. In this assessment of primary dysmenorrhea will be done with a self-administered questionnaire which will be asking questions relating to pelvic health, medical conditions and history of any other gynaecological conditions will be taken so as to differentiate between females with secondary dysmenorrhea. Severity of menstrual symptoms will be assessed using MDQ.

Females will be given structured exercise regime which will include – Core strengthening by Pelvic Bridging (Velammal et al 2016), cat and camel exercise (Rajalaxmi et al 2016), Abdominal draw-in maneuver (Bhalodia et al 2016), knee to chest (Mahishale et al 2016); Stretching by Bilateral Hamstring stretch (Gamit et al 2014) Bilateral quadriceps stretch (Ibrahim et al 2023), Bilateral adductor stretch (Ibrahim et al 2023), abdominal stretch (Upganlawar et al 2023) and relaxation by deep breathing exercises. (George et al 2019) All the exercises will be performed for 4 weeks and assessment of menstrual symptoms will be done again.

After completion of the pilot study, phase two of this research will initiate and in total 4 groups will be made as follows-

Group A: Structured exercise regime in luteal phase

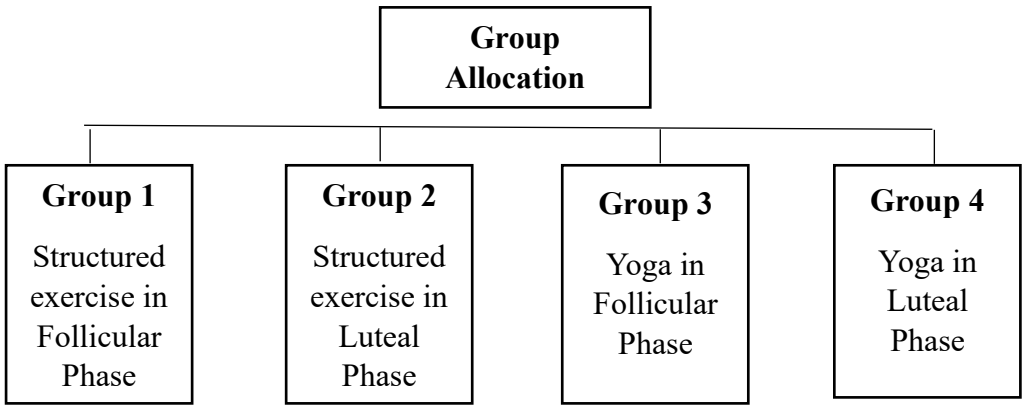
Group B: Structured exercise regime in follicular phase

Group C: Yoga in luteal phase

Group D: Yoga in follicular phase

10 days will be selected each from luteal and follicular phase, in which exercises and yoga will be instructed to the females through live/online sessions.

All exercises of Structured exercise protocol will be done for 10 times, with 10 seconds hold with rest period of 10 seconds for consecutive 3 menstrual cycle.



Females will be randomly allocated to the group by chit-method; each group will be allocated with 28 females.

Evaluation of QoL will be done by Health-related quality of life questionnaire, by which number of days affected by PD will be estimated.

Assessment of pelvic alignment: The participants will be asked to stand with feet shoulder width apart. For anterior-posterior tilt; anterior superior iliac spine (ASIS) & posterior superior iliac spine (PSIS) will be palpated, and will be marked with a marker. One arm of the caliper will be kept at ASIS & other on PSIS. Distance between both the landmarks and the angle formed between them will be measured. For lateral pelvic tilt; iliac crests of right and left side will be palpated and marked with a marker, at the highest height of iliac crest the caliper will be kept and angle formed will be recorded.

After the baseline assessment of menstrual symptoms severity, quality of life and pelvic alignment; treatment will be given in the above mentioned four groups.

In group 1, the structured exercises will be performed by females in the selected 10 days of luteal phase

In group 2, the structured exercises will be performed by females in the selected 10 days of follicular phase

In group 3, yoga will be performed by the females in the selected 10 days of luteal phase

In group 4, yoga will be performed by the females in the selected 10 days of follicular phase

Yoga will be taken from a study done by Anisha et al 2022; the study has explained maximum number of yoga asanas which have been proven to be beneficial for females with PD. The asanas include: Warrior pose, Fixed angle pose, Downward Hero pose, Camel pose, Reclining Fixed Angle Pose, Reclining Hero Stretch, Bow pose, Extended triangle pose, Seated wide angle pose, Cobra pose.

All the poses will be repeated for 5 times, 10 seconds hold with 30 seconds rest period after 2 poses. [Mrunmayee et al 2022]

The regime will be performed for 3 menstrual cycles, after which the assessment of menstrual symptoms, quality of life and pelvic alignment will be done again and statistical analysis will be performed to get the results.

EXPECTED OUTCOMES

Both structured exercise regime and yoga will show effective results in management of menstrual symptoms, QoL and pelvic alignment. This study will provide a better clarification about which menstrual phase will be better for the management of primary dysmenorrhea, also association between pelvic alignment and primary dysmenorrhea can be found.

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Manav Rachna International Institute of Research and Studies

(Deemed to be University)

Faculty of Allied Health Sciences

Department of Physiotherapy

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Consent Form

I, Sukriti Raj, PhD Scholar, 22/Ph.D./S/002, Faculty of Allied health Science, Manav Rachna International Institute of Research & Studies is working on a Research Project, titled,

"EFFECTS OF STRUCTURED EXERCISES AND YOGA DURING FOLLICULAR AND LUTEAL PHASE ON PELVIC ALIGNMENT, MENSTRUAL DISTRESS AND QUALITY OF LIFE IN PRIMARY DYSMENORRHEA."

Purpose of the Study

The purpose of the study is to find effective treatment option for the management of primary dysmenorrhea, the study will find which menstrual cycle phase is better for the management of menstrual symptoms, Quality of Life and pelvic alignment.

Duration of Participation

The estimated duration of each subject participation is approximately 3 menstrual cycles.

Explanation of Procedure

If you decide to participate, you will be asked to, provide consent for the collection and analysis of your data.

Potential Benefit of Participation

While specific benefits cannot be guaranteed, potential benefits of participating in this research is that it will provide better treatment options for menstrual pain which will improve Quality of life of females with primary dysmenorrhea.

Compensation

Financial Considerations

There are no special fees for participating in this study. However, the cost for participating will be borne by the Principal Investigator (PI) of the project. This includes the structured exercise program and yoga, which will be instructed and sessions will be free of cost.

Voluntary Nature of the Study

The participation of the patient in the study is purely voluntary in nature.

Right to withdraw

Participants are free to withdraw their consent to participate in this study anytime. Refusal to participate or withdrawal will not affect your future care and will involve no penalty to you. In the event, new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

Assurance of Anonymity and Confidentiality

The identity of the patient and data collected will remain absolutely confidential and anonymous. Furthermore, only averaged data will be shared and/ or published, thus maintaining anonymity of the patient.

Potential Risks or Discomforts

The potential risks associated with participating in this study are no or minimal. However, some individuals may experience temporary muscle soreness or fatigue due to engaging in the exercise and therapy sessions. Every effort will be made to minimize these risks by evaluation of preliminary information relating to your health and fitness and by careful observations during the procedure.

Contact Information:

Sukriti Raj

Ph.D Scholar,

Sai Apartments, Sector 13

Rohini, New Delhi

Contact No: +91 8586822704

(Aadhar No: 326292481703)

Declaration

-I confirm that I have read and understood the information and purpose of the study

-I have been informed about the quantity of data to be taken and the use that will be made of the data.

-I agree to the data being used for immediate routine measurements, and for relevant results

to be provided to me.

-I agree that my data may be stored for future research. This is on the understanding that the investigations will be for medical research only and my results will be kept confidential.

-I have read this form and the research study has been explained to me.

-I have been given the opportunity to ask questions and my questions have been answered to my satisfaction.

-If I have additional questions, I have been told who to contact

-I agree to participate in the research study described above. I can ask for a copy of this consent form after I sign it if I want to.

Participant's Name & Signature :

Participant Aadhar card No :

PAN No :

Please attach the copy of Aadhar card.

Name of the researcher & Signature:

Ph.D Scholar,

Sai Apartments, Sector 13

Rohini, New Delhi

Contact No: +91 8586822704

(Aadhar No: 326292481703)

Name of the Supervisor & Signature:

Dr. Kshitija Bansal

Professor

Department of Physiotherapy

Faculty of Allied Health Sciences

Manav Rachna International Institute of Physiotherapy

Faridabad, Haryana

Contact No: 9810314488

Manav Rachna International Institute of Research and Studies
(Deemed to be University)
School of Allied Health Sciences
Department of Physiotherapy

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मैं**, सुकृति राज**, पीएचडी स्कॉलर, 22/पीएचडी/एस/002, संबद्ध स्वास्थ्य विज्ञान संकाय, मानि रचना इंटरनेशनल इंस्टीट्यूट ऑफ ररसचच एंड स्टडीज एक शोध पररयोजना पर काम कर रही हं, वजसका शीर्चक है, "फॉवलक्यूलर और ल्यूवटयल चरण के प्रभाि - पेल्विक संरेखण, मावसक धमच संकट और प्राथवमक कष्टार्चि में जीिन की गुणित्ता पर आधाररर् संरवचर् व्यायाम और योग।

इस अध्ययन का उद्देश्य

अध्ययन का उद्देश्य प्राथवमक कष्टार्चि के प्रबंधन के वलए प्रभाि ी उपचार विकल्प ढूंढना है, अध्ययन से पर्ा चलेगा वक मावसक धमच के लक्षणों, जीिन की गुणित्ता और श्रोवण संरेखण के प्रबंधन के वलए मावसक धमच चक्र का कौन सा चरण बेहर्र है।

भागीदारी की अवति

प्रत्येक विर्य की भागीदारी की अनुमावनर् अिवध लगभग 3 मावसक धमच चक्र है।

प्रतिया की व्याख्या

यवद आप भाग लेने का वनणचय लेर्े हैं, र्ो आपसे आपके डेटा के संग्रह और विश्लेर्ण के वलए सहमवर् प्रदान करने के वलए कहा जाएगा।

भागीदारी का संभातवि लाभ

हालांवक विवशष्ट लाभों की गारंटी नहीं दी जा सकर्ी है, लेवकन इस शोध में भाग लेने का संभाविर् लाभ यह है वक यह मावसक धमच के ददच के वलए बेहर्र उपचार विकल्प प्रदान करेगा वजससे प्राथवमक कष्टार्चि से पीवि़र् मवहलाओं के जीिन की गुणित्ता में सुधार होगा।

मुआवजा

वित्तीय विचार

इस अध्ययन में भाग लेने के वलए कोई विशेर् शुल्क नहीं है। हालाँवक, भाग लेने की लागर् पररयोजना के प्रधान अन्वेर्क (पीआई) द्वारा िहन की जाएगी। इसमें संरवचर् व्यायाम कायचक्रम और योग शावमल हैं, वजनका वनदेश वदया जाएगा और सत्र वनिःशुल्क होंगे।

अध्ययन की स्वैच्छिक प्रकृति

अध्ययन में रोगी की भागीदारी पूरी र्रह से स्वैल्विक प्रकृवर् की है।

वापस लेने का अतिकार

प्रवर्भागी इस अध्ययन में भाग लेने के वलए अपनी सहमवर् वकसी भी समय ि◌ापस लेने के वलए स्वरं्त्र हैं। भाग लेने से इनकार करने या ि◌ापस लेने से आपकी भविष्य की देखभाल प्रभावि् नहीं होगी और आपको कोई जुमाचना नहीं लगेगा।

ऐसी ल्वथथवर् में, नई जानकारी उपलब्ध हो जार्ी है जो इस अध्ययन में भाग लेने की आपकी इि को प्रभावि् कर सकर्ी है, यह जानकारी आपको दी जाएगी र्ावक आप अपनी भागीदारी जारी रखने या न रखने के बारे में एक सूवचर् वनणचय ले सकें।

गुमनामी और गोपनीयिा का आश्वासन

मरीज की पहचान और एकत्र वकया गया डेटा वबल्कुल गोपनीय और गुमनाम रहेगा। इसके अलाि◌ा, केि◌ल औसर् डेटा ही साझा और/या प्रकावशर् वकया जाएगा, इस प्रकार रोगी की गुमनामी बरकरार रहेगी।

संभातवि जोच्छिम या असुतविाएँ

इस अध्ययन में भाग लेने से जुि◌े संभावि् जोल्वखम न के बराबर हैं या न्यूनर्म हैं। हालाँवक, कुछ व्यल्वियों को व्यायाम और वचवकत्सा सत्रों में शावमल होने के कारण अथथायी मांसपेवशयों में ददच या थकान का अनुभि हो सकर्ा है। आपके स्वास्थ्य और वफटनेस से संबंवधर् प्रारंवभक जानकारी का मूल्यांकन करके और प्रवक्रया के दौरान सावि◌धानीपूि◌चक अिलोकन करके इन जोल्वखमों को कम करने के वलए हर संभि प्रयास वकया जाएगा।

संपकक जानकारी:

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घोषणा

-मैं पुवष्ट करर्ी हं वक मैंने अध्ययन की जानकारी और उद्देश्य को पढ़ और समझ वलया है

-मुझे वलये जाने ि◌ाले डेटा की मात्रा और डेटा के उपयोग के बारे में सूवचर् वकया गया है।

-मैं र्कल वनयवमर् माप के वलए उपयोग वकए जाने ि◌ाले डेटा और मुझे प्रासंवगक पररणाम प्रदान करने के वलए सहमर् हं।

-मैं सहमर् हं वक मेरा डेटा भविष्य के शोध के वलए संग्रहीर् वकया जा सकर्ा है। यह इस समझ पर है वक जांच केि◌ल वचवकत्सा अनुसंधान के वलए होगी और मेरे पररणाम गोपनीय रखे जाएंगे।

-मैंने यह फॉमच पढ़ा है और शोध अध्ययन के बारे में मुझे समझाया गया है।

-मुझे प्रश्न पूछने का अिसर वदया गया है और मेरे प्रश्नों का मेरी संर्ुवष्ट के अनुरूप उत्तर वदया गया है।

-यवद मेरे पास अवर्ररि प्रश्न हैं, र्ो मुझे बर्ाया गया है वक वकससे संपकच करना है

-मैं ऊपर िवणचर् शोध अध्ययन में भाग लेने के वलए सहमर् हं। यवद मैं चाहं र्ो मैं इस सहमवर् प्रपत्र पर हस्ताक्षर करने के बाद इसकी एक प्रवर् मांग सकर्ी हं।

प्रवर्भागी का नाम एि हस्ताक्षर:

प्रवर्भागी का आधार काडच नंबर :

पैन नंबर:

शोधकर्ाच का नाम और हस्ताक्षर:

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Screening Questionnaire for Primary Dysmenorrhea

This is a screening questionnaire for the research tilted "Effects of follicular & luteal based exercises & yoga on pelvic alignment, menstrual distress & quality of life in primary dysmenorrhea" Please read all the questions carefully and give your honest response. There are no right or wrong answers.

You have to give one answer out of the given options except Question No 11 and 12. For questions 11 & 12 you can answer more than one options.

Part A: Demographic details

1. Name –
2. Age –
3. Occupation –
4. Marital status -

   □ Married □ Unmarried □ Widowed/separated/ Divorced

5. Contact No.-
6. Email ID-

Part B- Menstrual Health Questions

7. Do you have menstrual cycle of 28-35 days?

   □ Yes □ No

8. At what age did you have your first periods/menses? _____
9. Do you suffer from menstrual cramps during your menses?

   □ Yes □ No

10. After initiation of your first menses, when did the menstrual cramps start?

    □ Within 6 months □ Within 1 year

    □ Within 1.5 years □ Within 2 years

    □ Others. If other, please specify _____

11. What areas in your body are painful while you are on your menses?

□ Abdomen □ Thigh □ Breasts

□ Low back □ Pelvic □ Legs

□ Others If others, please specify the area _____

12. What all symptoms do you have during your menses?

□ Nausea □ Bloating □ Tiredness

□ Diarrhoea □ Dizziness □ Constipation

□ Others If others, please specify the symptom _____

13. Do you take any home remedy or medications for relieving the symptoms?

□ Yes □ No

If yes, please specify _____

14. For how many days do you have bleeding?

□ 1 – 3 days □ 3 – 5 days

□ 3 – 7 days □ Others

If others, please specify _____

15. Have the number of days of bleeding during menstruation changed in the past 3 months?

□ Increased □ Decreased □ No change

16. How many pads get soaked in one cycle? _____

17. Are you sexually active?

□ Yes □ No

18. Have you suffered from vaginal bleeding other than your menses in the last 3 months?

□ Yes □ No

19. Have you suffered from menstrual like pain other than the actual days of menstruation in the previous 3 months?

□ Yes □ No

20. Have your symptoms increased in the past 3 months?

□ Yes □ No

If yes, then, have you consulted any gynaecologist for the same?

□ Yes □ No

21. Have you been diagnosed with PCOD, PCOS, ovarian cyst, endometriosis or any other pelvic pathology?

□ Yes □ No

If yes, specify the condition _____

22. Have you been diagnosed with any medical condition?

□ Thyroid □ Diabetes

□ Others

If others, please specify _____

23. Do you take any medications for any medical condition?

□ Yes □ No

If yes, specify_____

24. Have you suffered from any urinary tract infection in the past 3 months?

□ Yes □ No

25. Do you take any contraceptive pills?

□ Yes □ No

26. Do you have any history of miscarriage/chemical pregnancy?

□ Yes □ No

27. Do you have a history of any surgery?

□ Yes □ No

If yes, please specify _____

Appendix 7

Menstrual Distress Questionnaire

Form C

Identifying Number:_____

DOB: _____

Today's Date:_____

Write the appropriate dates of your most recent menstrual period (flow) in the space marked "A" below. Then write the dates of the menstrual period which preceded the most recent on in the space marked "D".

previous menstrual flow			most recent flow
from _____ to _____	other times during most recent cycle	four days before recent flow	from _____ to _____
D	C	B	A

On the next two pages is a list of symptoms that women sometimes experience. Please describe your experience of each of these symptoms during the three time periods listed below:

Col. 1 during the four days before your most recent menstrual flow (area B on the diagram).

Col. 2 during your most recent menstrual flow (the dates shown in area A on the diagram below).

Col. 3 during the remainder of your most recent menstrual cycle (area C).

Note: The answers you put in column 1, 2, and 3 should be accurate for your experience during your most recent menstrual cycle. Please do not report your general experience. Also, please report any experience of these symptoms whether or not they seem to you to be related to your menstrual cycle.

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For each answer choose the category that best describes your experience of that symptom during that time. Write the number of that category in the space provided. Even if none of the categories is exactly correct, choose the one that best describes your experience. Do not leave any blank spaces.

Descriptive Categories

O - No experience of symptoms
1 - Present, mild
2 - Present, moderate
3 - Present, strong
4 - Present, severe

		1 Four days before	2 Most recent flow	3 Remainder of cycle
		A	B	C
1.	Muscle stiffness	_____	_____	_____
2.	Weight gain	_____	_____	_____
3.	Dizziness, faintness	_____	_____	_____
4.	Loneliness	_____	_____	_____
5.	Headache	_____	_____	_____
6.	Skin blemish or disorder	_____	_____	_____
7.	Cold sweats	_____	_____	_____
8.	Anxiety	_____	_____	_____
9.	Mood swings	_____	_____	_____
10.	Cramps	_____	_____	_____
11.	Painful or tender breasts	_____	_____	_____
12.	Nausea, vomiting	_____	_____	_____
13.	Crying	_____	_____	_____
14.	Backache	_____	_____	_____
15.	Swelling (breasts, abdomen)	_____	_____	_____
16.	Hot flushes	_____	_____	_____
17.	Irritability	_____	_____	_____
18.	Tension	_____	_____	_____
19.	Fatigue	_____	_____	_____
20.	Feeling sad or blue	_____	_____	_____
21.	General aches and pains	_____	_____	_____
22.	Restlessness	_____	_____	_____

		1 Four days before	2 Most recent flow	3 Remainder of cycle
		A	B	C
23.	Insomnia	_____	_____	_____
24.	Poor school or work performance	_____	_____	_____
25.	Affectionate	_____	_____	_____
26.	Feelings of suffocation	_____	_____	_____
27.	Forgetfulness	_____	_____	_____
28.	Take naps, stay in bed	_____	_____	_____
29.	Orderliness	_____	_____	_____
30.	Chest pains	_____	_____	_____
31.	Confusion	_____	_____	_____
32.	Poor judgement	_____	_____	_____
33.	Stay at home	_____	_____	_____
34.	Excitement	_____	_____	_____
35.	Ringing in the ears	_____	_____	_____
36.	Difficulty concentrating	_____	_____	_____
37.	Avoid social activities.....	_____	_____	_____
38.	Feeling of well-being	_____	_____	_____
39.	Heart pounding	_____	_____	_____
40.	Distractible	_____	_____	_____
41.	Decreased efficiency	_____	_____	_____
42.	Bursts of energy, activity	_____	_____	_____
43.	Numbness, tingling	_____	_____	_____
44.	Minor accidents	_____	_____	_____
45.	Blind spots, fuzzy vision	_____	_____	_____
46.	Poor motor co-ordination	_____	_____	_____
47.	Increased appetite	_____	_____	_____

Health-Related Quality of Life Survey: CDC HRQOL–14

Please circle your answers and fill in the blanks about yourself or your child. If at any point you would like to skip a question or opt out of the survey, you may do so.

I. Healthy Days Core Module (CDC HRQOL-4)

1. Would you say that in general your health is

    a. Excellent
    b. Very good
    c. Good
    d. Fair
    e. Poor
    f. Don't know/not sure
    g. Refused

2. Now thinking about your physical health, which includes physical illness and injury, for how many days **during the past 30 days** was your physical health not good?

    a. Number of days: ____
    b. None*
    c. Don't know/not sure
    d. Refused

3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days **during the past 30 days** was your mental health not good?

    a. Number of days: ____
    b. None*
    c. Don't know/not sure
    d. Refused

***If both Q2 and Q3= "None", skip question 4**

4. **During the past 30 days**, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?

    a. Number of days: ____
    b. None
    c. Don't know/not sure
    d. Refused

II. Activity Limitations Module

1. Are you LIMITED in any way in any activities because of any impairment or health problem?

    a. Yes
    b. No
    c. Don't know/not sure
    d. Refused

2. What is a MAJOR impairment or health problem that limits your activities? Circle answers.

Arthritis/rheumatism	Stroke problem
Back or neck problem	High blood pressure
Bone/joint injury	Diabetes
Walking problem	Cancer
Lung/breathing problem	Depression/anxiety
Hearing problem	Other impairment
Eye/vision problem	Unsure
Heart problem	Refused

3. For HOW LONG have your activities been limited because of your major impairment or health problem?

    a. Days
    b. Weeks
    c. Months
    d. Years
    e. Don't know/not sure
    f. Refused

Continue from Activity Limitations Module:

4. Because of any impairment or health problem, do you need the help of other persons with your PERSONAL CARE needs, such as eating, bathing, dressing, or getting around the house?

a. Yes
b. No
c. Don't know/not sure
d. Refused

5. Because of any impairment or health problem, do you need the help of other persons in handling your ROUTINE needs, such as everyday household chores, doing necessary business, shopping, or getting around for other purposes?

a. Yes
b. No
c. Don't know/not sure
d. Refused

III. Healthy Days Symptoms Module

1. **During the past 30 days**, for about how many days did PAIN make it hard for you to do your usual activities, such as self-care, work, or recreation?

a. Number of Days: ____
b. None
c. Don't know/not sure
d. Refused

2. **During the past 30 days**, for about how many days have you felt SAD, BLUE, or DEPRESSED?

a. Number of Days: ____
b. None
c. Don't know/not sure
d. Refused

3. **During the past 30 days**, for about how many days have you felt WORRIED, TENSE, or ANXIOUS?

a. Number of days: ____
b. None
c. Don't know/not sure
d. Refused

4. **During the past 30 days**, for about how many days have you felt you did NOT get ENOUGH REST or SLEEP?

a. Number of Days: ____
b. None
c. Don't know/not sure
d. Refused

5. **During the past 30 days**, for about how many days have you felt VERY HEALTHY AND FULL OF ENERGY?

a. Number of days: ____
b. None
c. Don't know/not sure
d. Refused

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. Think *only* about those physical activities that you did for at least 10 minutes at a time.

1. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, aerobics, or fast bicycling?

   _____ **days per week**

   ☐ No vigorous physical activities → ***Skip to question 3***

2. How much time did you usually spend doing **vigorous** physical activities on one of those days?

   _____ **hours per day**

   _____ **minutes per day**

   ☐ Don't know/Not sure

Think about all the **moderate** activities that you did in the **last 7 days**. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal. Think only about those physical activities that you did for at least 10 minutes at a time.

3. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads, bicycling at a regular pace, or doubles tennis? Do not include walking.

   _____ **days per week**

   ☐ No moderate physical activities → ***Skip to question 5***

4. How much time did you usually spend doing **moderate** physical activities on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

Think about the time you spent **walking** in the **last 7 days**. This includes at work and at home, walking to travel from place to place, and any other walking that you have done solely for recreation, sport, exercise, or leisure.

5. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time?

_____ **days per week**

☐ No walking → ***Skip to question 7***

6. How much time did you usually spend **walking** on one of those days?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

The last question is about the time you spent **sitting** on weekdays during the **last 7 days**. Include time spent at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading, or sitting or lying down to watch television.

7. During the **last 7 days**, how much time did you spend **sitting** on a **week day**?

_____ **hours per day**

_____ **minutes per day**

☐ Don't know/Not sure

This is the end of the questionnaire, thank you for participating.

MANAV RACHNA
Vidyanatarikshah

Ref. No. ED & Deanres./1399

OFFICE OF ED & DEAN RESEARCH
Research Ethics Committee
MRIIRS, FARIDABAD
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19th April, 2024

Dr. Kshitija Bansal
Supervisor
Professor ,Department of Physiotherapy,
School of Allied Health Sciences
MRIIRS,
Faridabad- 121001

Dear Dr. **Kshitija Bansal**
The MRIIRS Ethics Committee has reviewed your request, for the ethical approval for the research project outlined below.

"EFFECTS OF FOLLICULAR AND LUTEAL PHASE – BASED STRUCTURED EXERCISES AND YOGA ON PELVIC ALIGNMENT, MENSTRUAL DISTRESS AND QUALITY OF LIFE IN PRIMARY DYSMENORRHEA"

Ms. Sukriti Raj
Research Scholar
MRIIRS
Registration number: 22/Ph.D/S/002

The case is discussed in the meeting of Ethical Committee, MRIIRS held on 02.04.2024 vide Online Mode at 2.30pm.

https://meet.google.com/afw-bphq-hwz

Further, on examining the research work undertaken vide video presentation mode given by the Research Scholar, as indicated above , it was resolved that ethical approval may be granted as the research scholar will obtain consent of participants i.e. females with primary dysmenorrheal.. Also consent letter format / form both English and Hindi has been submitted. The required

documents as asked in the meeting have been submitted today i.e. 19.04.2024 by Dr. Kshitija Bansal, Professor, Supervisor, School of Allied Health Sciences, MRIIRS

Approval No:	EC/2023-24/048
Approval Date:	19/04/2024
Expiry Date:	31/03/2026
Ethics Committee Decision	Approved

The standard conditions of this approval are:

a) Conduct the project strictly in accordance with the proposal submitted and granted ethics approval. Including any amendments made to the proposal required by the MRIIRS Ethics Committee.

b) Report (email: dean.research@mriu.edu.in) immediately of any complaints or other issues in relation to the research project which may warrant review of the ethical approval of the project.

c) Provide a 'progress report' for every year of approval.
d) Provide a 'final report' when the project is complete.
e) Advise in writing if the project has been discontinued

Please note that failure to comply with the conditions of approval and the **"INDIAN COUNCIL OF MEDICAL RESEARCH. 2017. NATIONAL ETHICAL GUIDELINES. FOR BIOMEDICAL AND HEALTH RESEARCH INVOLVING HUMAN"** may result in withdrawal of approval for the research project.

Sarita 19/4/24

Dr Sarita Sachdeva
ED & Dean Research
MRIIRS

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SIMILARITY VERIFICATION CERTIFICATE

Title: ...Effects of structured exercises and yoga during follicular and luteal phase on pelvic alignment, menstrual distress and quality of life in Primary Dysmenorrhea.

Researcher:..Sukriti Raj Registration Number:..22/Ph.D/002

Supervisor:..Dr. Kshitija Bansal Department:....SAHS.....

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Research Scholar

Research Supervisor

EFFECTS OF STRUCTURED EXERCISES AND YOGA DURING FOLLICULAR AND LUTEAL PHASE ON PELVIC ALIGNMENT, MENSTRUAL DISTRESS AND QUALITY OF LIFE IN PRIMARY DYSMENORRHEA

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by Sukriti Raj

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EFFECTS OF STRUCTURED EXERCISES AND YOGA DURING FOLLICULAR AND LUTEAL PHASE ON PELVIC ALIGNMENT, MENSTRUAL DISTRESS AND QUALITY OF LIFE IN PRIMARY DYSMENORRHEA

SHORT SYNOPSIS

By

Sukriti Raj

22/Ph.D/S/002

Under the supervision of

Dr. Kshitija Bansal

Professor, MRIIRS

SCHOOL OF ALLIED HEALTH SCIENCES

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ABSTRACT

Primary dysmenorrhea (PD) is defined as menstrual cramps without any pelvic origin pathology, which occur from the first day till third day of menstruation phase. During each menstrual cycle sex hormones fluctuates which can impact muscle strength and endurance. Primary dysmenorrhea is most common gynaecological problem which can cause decrease in quality of life (QoL) in females. This study will have 4 groups in which yoga and structured exercise regime will be performed by selected females having primary dysmenorrhea, in luteal or follicular phase. Assessment of primary dysmenorrhea will be done by a self-

administered questionnaire, severity of menstrual symptoms will be assessed by Menstrual Distress Questionnaire (MDQ), QoL by Health-Related Quality of Life questionnaire and pelvic anterior and posterior tilt by PALM palpation meter. Baseline assessment and post intervention assessment of the parameters will be done and using SPSS analysis will be performed.

Key words – Primary dysmenorrhea, menstrual distress, follicular phase, luteal phase, structured exercises, yoga, pelvic alignment, quality of life.